

Remarks/Argument

Applicant have received and carefully reviewed the Final Office Action mailed on December 30, 2009. Claims 43, 44, 46, 49, and 52 have been rejected. Claims 43, 44, 46, 49, 52, 55, and 57-63 are currently pending, of which claims 55 and 57-63 have been previously withdrawn from consideration

Drawings

On page 2 of the Final Office Action, the drawings were objected to as failing to comply with 37 C.F.R. 1.84(p)(5) because "they do not include reference sign(s) for the first and second balloon nor are there reference signs or numbers for these elements in the Specification." Applicant respectfully traverses the objection.

The Final Office Action cites to 37 C.F.R. 1.84(p)(5) for authority for the objection. However, 37 C.F.R. 1.84(p)(5) states that:

Reference characters not mentioned in the description shall not appear in the drawings. Reference characters mentioned in the description must appear in the drawings.

Nothing in the cited authority appears to provide any basis for objecting to both the drawings and the specification as not including reference characters. Nowhere does the Final Office Action appear to identify any reference characters not mentioned in the description that appear in the drawings or any reference characters that are mentioned in the description that do not appear in the drawings.

Furthermore, it appears that the Final Office Action is attempting to combine to form paragraphs found in MPEP 608.02(e), specifically, the two following form paragraphs:

¶ 6.22.06 *Drawings Objected to, Reference Numbers Not in Drawings*
The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: [1]. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted

by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

¶ 6.22.07 Drawings Objected to, Reference Numbers Not in Specification

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: [1]. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicant respectfully submits that this combination is clearly improper. Further, nothing in 37 CFR 1.84(p)(5) appears to provide any basis for this objection. As such, Applicant submits that the drawings and specification are in compliance with 37 C.F.R. 1.84(p)(5). Withdrawal of the objection is respectfully requested. If this objection is to be maintained, Applicant respectfully requests proper authority be provided to support the objection.

Claim Rejections - 35 U.S.C. § 103

On pages 2-3 of the Final Office Action, claims 43, 44, 46, and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Wittenberger et al. (U.S. Patent No. 6,575,933) in view of Hammack et al. (U.S. Patent No. 6,679,906). Applicant respectfully traverses the rejection.

Turning to claim 43, which recites:

43. (Previously Presented) A device for minimally invasive medical treatment in a body of a patient, comprising:
a tubular member having a proximal end and a distal end;
a cryo therapy apparatus connected to the distal end of the tubular member, wherein the cryo therapy apparatus comprises a first balloon and a second balloon, the first and second balloons arranged to define an inner

chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails; and

an optical sensor to monitor temperatures created by use of the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus;

wherein the cryo therapy apparatus is sized and arranged for vascular introduction.

Neither Wittenberger et al. or Hammack et al., taken either alone or in combination, appear to disclose many elements of claim 43, including for example, “a cryo therapy apparatus connected to the distal end of the tubular member, wherein the cryo therapy apparatus comprises a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails”.

In the Final Office Action, the Examiner cites to element 610 of Wittenberger et al. as providing a first balloon and element 630 as providing a second balloon. With regards to elements 610 and 630, Wittenberger et al. recites:

Specifically, FIG. 13 shows a catheter whose proximal segment 600 preferably includes within it an air supply line 605 and a fluid supply line 620. The air supply line 605 terminates in an inner balloon 610, shown in an expanded condition. It should be noted that air inflation of the inner balloon 610 is merely one of a number of possible expansion methods. The inner balloon 610 has surrounding it a plurality of members 630, spaced radially apart around a longitudinal axis of the inner balloon 610. In this expanded condition, the members 630 contact an inner side 617 of an outer balloon 615. Cryogenic fluid may preferably be introduced into the space 618 created in this arrangement between the inner balloon 610 and the outer balloon 615 through fluid supply line 620.

(Emphasis added, column 8, lines 25-38.) As can be seen, Wittenberger et al. appears to disclose an inner balloon 610 surrounded at least in part by an outer balloon 615, the inner

balloon 610 appears to be inflated by air or other suitable expansion method and the cryogenic fluid appears to be introduced into the space 618 created between the inner balloon 610 and the outer balloon 615. Nothing in this passage of Wittenberger et al. appears to disclose “a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails”, as recited in claim 43. Further, nowhere does the Final Office Action appear to cite any portion of Wittenberger et al. as disclosing this feature. Notably, if the balloon 615 of Wittenberger et al. (which defines the space 618 that the cryogenic fluid appears to be introduced into) fails, there is no second balloon configured to retain the coolant within the cryo therapy apparatus. Additionally, nowhere does the Final Office Action appear to cite any portion of Hammack et al. as curing the noted shortcomings of Wittenberger et al. For at least these reasons, claim 43 is believed to be patentable over Wittenberger et al. in view of Hammack et al. For similar and other reasons, claims 44, 46, and 49, which depend from claim 43 and include additional distinguishing features, are also believed to be patentable over Wittenberger et al. in view of Hammack et al. Withdrawal of the rejection is respectfully requested.

On page 4 of the Final Office Action, claim 52 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Wittenberger et al. in view of LePivert (U.S. Patent No. 6,551,309). Applicant respectfully traverses the rejection.

Claim 52 recites:

52. (Previously Presented) A device for minimally invasive medical treatment in a body of a patient, comprising:

a tubular member having a proximal end and a distal end;

a cryo therapy apparatus connected to the distal end of the tubular member and comprising a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails and prevent loss of the coolant to the body of the patient; and

an optical imaging apparatus near the distal end of the tubular member to monitor temperatures resulting from use of the cryo therapy apparatus,

wherein the cryo therapy apparatus is sized and arranged for vascular introduction.

Nothing in Wittenberger et al. or Hammack et al., taken either alone or in combination, appear to disclose many elements of claim 52, including for example, "a cryo therapy apparatus connected to the distal end of the tubular member and comprising a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails and prevent loss of the coolant to the body of the patient". For similar reasons discussed above with reference to claim 43, as well as other reasons, claim 52 is believed to be patentable over Wittenberger et al. in view of LePivert. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Further examination and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
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By his Attorney,

Date: _____

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